REMARKS

The Official Action of June 23, 2003, and the prior art cited and relied upon therein have been carefully reviewed. The claims in the application are now claims 1-34, including non-elected claims 32 and 33, and applicants' claims define patentable subject matter warranting their allowance. Accordingly, the applicants respectfully request favorable reconsideration and allowance.

The restriction requirement as it appears in the Official Action is not the same as the one made orally, nor is it consistent with applicants' oral election. Accordingly, it is first respectfully traversed solely on this basis.

The oral restriction and election requirement was made on or about April 18, 2003, between Group I directed to the device and **comprising claims 1-31**, and Group II directed to the system (apparatus), comprising claims 32 and 33. There were only two (2) groups, not three (3) groups. On or about June 2, 2003, applicants orally elected Group I, **claims 1-31**[1], and the species of claim 24, and **this was confirmed in applicants' Communication filed June 2, 2003.**

Accordingly, applicants respectfully but strongly traverse the withdrawal of claims 22, 23 and 28 which were

[1] New claim 34 also falls within the elected subject matter.

included in the claims orally elected by applicants. As applicants did not agree that claims 22, 23 and 28 would be withdrawn, applicants deserve an examination of these claims, and so respectfully request such an examination. Applicants hereby respectfully affirm the election of claims 1-31 with traverse and without prejudice.

Second, the written restriction requirement on page 2 of the outstanding Office Action of June 23, 2003, the PTO takes the position that claims 22 and 23 are patentably distinct from the remainder of the Group I claims as process of making and product made. Respectfully, this is clearly incorrect. **Claims 22, 23 and 28 are product claims, both being directed to the "device"**, with claim 22 being directly dependent on claim 1 and claim 23 being dependent on claim 22, and with the typographical error in claim 28 having been corrected above. (Incidentally, in the restriction requirement as delineated at the top of page 2 of the outstanding Office Action, claim 22 has been included in **both** Group I and Group II.)

Third, as regards claims 32 and 33, orally indicated as belonging to Group II and indicated in the Office Action as belonging to Group III, applicants request withdrawal of the requirement on the basis that the system for forming the cylindrical cover is closely tied to the nature of the cover

itself. Consequently, claims 32 and 33 are sufficiently closely related to the elected subject matter so that it should also be searched and examined in the present application, as it would not constitute a serious burden to do so (MPEP 803).

Applicants respectfully request withdrawal of the restriction requirement and examination of all the claims on the merits.

Applicants' specification has been objected to because of certain stated "informalities". In deference to the examiner's views, appropriate amendments have been made in the specification. These changes impose no limitations on applicants' invention.

No rejections have been imposed under Section 112. Accordingly, applicants understand that the PTO deems applicants' claims to be fully in accordance with the requirements of Section 112.

Nevertheless, some claim amendments have been made to better comply with U.S. practice. Thus, typographical errors have been corrected in claims 21, 27, 28, 32 and 33. The Markush language has been corrected in claims 2 and 8. Claim 1 has been amended to improve its form, as have claims

15 and 16. Claim 14 has been amended so as to avoid any confusion with the sixth paragraph of Section 112.

Applicants are proceeding in reliance on their understanding that the PTO considers applicants' claims to be fully in accordance with Section 112.

New claim 34 has been added. This is a new independent claim similar to claim 1, but also specifying means for detaching the cover from the surface and removing the detached cover from the body while device remains within the body, without damage to the body. This new claim is patentable for the same reasons as claim 1, as pointed out below.

Claims 1-3, 8-12 and 25-27 have been rejected under Section 102 as anticipated by Wepsie USP 3,598,127 ("Wepsie"). This rejection is respectfully traversed.

Applicants' claim 1, and indeed all of applicants' claims, call for the medical device to have a surface covered by at least one detachable cover, such cover being detachable from the covered surface so as to be removable from the device after the device has been inserted into the body. Wepsie does not show such subject matter.

It is true that Wepsie discloses a catheter for reducing chances of infection developing in an organ, the

catheter having a cover in the form of an outer tube 21 through which an antibacterial substance is capable of permeating to the outer surface of the tube 21. However, Wepsie does not show a cover which is detachable from the surface of the catheter. No provision is disclosed in Wepsie whereby the tube 21 could possibly be removed while the catheter remains in the body of the patient.

Wepsie does not anticipate any of applicants' claims. Accordingly, applicants respectfully request withdrawal of the rejection.

Claims 1, 2, 4, 7, 9-11, 13 and 18 have been rejected under Section 102 as anticipated by Coulter USP 5,417,666 ("Coulter"). This rejection is also respectfully traversed.

Coulter discloses a catheter with a sterile catheter shield in the form of a sheath which is inserted into the urethra prior to insertion of the catheter into the urethra. After insertion of the catheter into the urethra, the sheath is removed. Coulter is acknowledged prior art discussed in the first paragraph on page 2 of applicants' specification.

Accordingly, it should be clear that Coulter does not show, as claimed, a "device having at least one surface covered by at least one detachable cover," because in Coulter the sheath and the catheter are two entirely separate

elements, never part of the same device. In other words, because the sheath is inserted into the urethra prior to the insertion of the catheter according to Coulter, the sheath cannot be considered to ever be attached to the catheter. Since the sheath is not attached to the catheter, it clearly cannot be detached from it. Therefore, the sheath is not a detachable cover of the catheter, as called for in applicants' claims.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 1, 2, 4-11, 14, 18 and 21 have been rejected under §102 as being anticipated by Holman et al U.S. 2002/0120324 (Holman)[2]. This rejection is respectfully traversed.

At first blush, Holman looks very relevant, but a more careful review of Holman shows that it also is fundamentally deficient. Thus, while Holman discloses a balloon catheter in which the balloon is contained within a sleeve, the sleeve is removed **prior to insertion of the catheter into the body.** As the sleeves of Holman have been

[2] Noting item (60) on the face of Holman, applicants assume, but have not checked, that the disclosures of U.S. patent 6,416,529; 6,152,944; and 5,893,868, are identical.

removed before insertion of the catheter, they cannot be removed from catheter after the catheter has been inserted in to the body, as required according to the present invention and as called for in applicants' claims. Holman accordingly does not anticipate any of applicants' claims.

The fact that the sleeves in Holman are removed **before** insertion of the catheter is not directly stated in Holman, but is quite clear from a careful study of this document. To start, reference is made to lines 7 and 8, and the last three lines of the Abstract which indicate that the sleeves are removed "prior to use of the catheter". This is also stated at the ends of paragraphs 0012 and 0014, and other locations of the Holman disclosure as well.

Paragraph 0076 explains the advantage of having a cover that is removed before use, and this repeated in paragraph 0102. Another advantage is given in paragraph 0083. These advantages all inher to the Holman device before insertion, whereby the Holman disclosure further implies removal of the shield before insertion.

Paragraph 0110 again states that the inner and outer sleeves are removed "prior to use", and this is followed up immediately by paragraph 0111 which then mentions delivery (insertion) of the balloon catheter of Holman, from which the

sleeves have already been removed as per paragraph 0110, no mention of the sleeves being made in paragraph 0111.

Similarly, from consecutive paragraphs 0085 and 0086, it is seen that the sleeves are first removed and then the balloon catheter is delivered into the patient.

Attention is also invited to the Holman figures which show that the sleeves only cover the distal end of the catheter, i.e. they do not extend the entire length thereof. From this, it should be clear that the sleeves cannot be removed after the catheter tip has been inserted into the patient. This is further made clear from consideration of paragraphs 0085 and 0110 (already mentioned above) which state that the outer sleeve is removed by "pulling it off" and the inner sleeve is removed in either a like manner or by pulling "tail 38" (Fig. 1). Because the sleeves, including the tail, are not assessable after insertion of the catheter into the body, the only reasonable conclusion is that the sleeves must be removed from the Holman catheter before such catheter is inserted into the body.

As stated above, Holman does not disclose what is called for in applicants' claim 1 and 34. Withdrawal of the rejection is in order and is respectfully requested.

Claims 1 and 24 have been rejected as anticipated by Kusleika U.S. 2002/0032406 (Kusleika). This rejection is respectfully traversed.

Kusleika discloses another balloon catheter, in particular a catheter for blood vessel dilation and drug delivery. In the Kusleika device, the balloon is contained within a sheath which is radially expandable and is either naturally porous or is provided with multiple pores, whereby the therapeutic agent perfuses through the sheath into the surrounding tissue (e.g. see the Abstract). After delivery to the site of deployment, the balloon is inflated, causing the sheath to expand until it contacts the interior of the vessel wall. The balloon is then deflated and catheter with the balloon is removed from the body, noting especially paragraphs 0054 and 0055.

Not only does Kusleika not disclose removal of the sheath while leaving the catheter in place, but Kusleika provides not the remotest inference of such a device being such a capability.

The rejection states that the Figs. 4-7 of Kusleika show that "when the balloon is expanded and then deflated, the cover sheath becomes detached from the surface." Applicants do not see any such disclosure in Kusleika, i.e. the sheath 22 always remains with the catheter, so that when the catheter is

withdrawn the sheath 22 is withdrawn with it. However, even it were assumed that the sheath 22 somehow separates from the reminder of the catheter, whereby the catheter could be withdrawn leaving the sheath 22 within the blood vessel, this would be opposite to the present invention where, after deliver, the cover is removed from the body while leaving the device, e.g. a catheter, within the body.

Kusleika does not anticipate any of applicants' claims. Accordingly, applicants respectfully request withdrawal of the rejection.

Claims 15, 16, and 31 have been rejected as obvious under §103 from Holman in view of Chin USP 5,571,172 (Chin). This rejection is respectfully traversed.

Claims 15, 16 and 31 depend from and thus incorporate the subject matter of claim 1. Chin has not been cited to make up for the aforementioned deficiencies of Holman, nor does it do so. Therefore, even if the combination were obvious (applicants make no comment on this point at the present time), the reconstructed Holman in view of Chin would not reach the subject matter of claim 1, let alone claims 15, 16 and 31.

Applicants respectfully request withdrawal of the rejection.

Claims 17 and 30 have been rejected as obvious under §103 from Holman in view of Malloney et al USP 5,188,606 (Malloney). This rejection is respectfully traversed.

The same arguments made immediately above against the rejection based on Holman in view of Chin apply equally to this rejection. Thus, claims 17 and 30 incorporate the features of claim 1. Malloney does not make up for the aforementioned deficiencies of Holman, and has not been cited for that purpose. Therefore, even if the combination were obvious (respectfully denied), the resultant reconstruction of Holman modified by Malloney would not reach the subject matter of the claim 1 portions of claims 17 and 30.

Applicants respectfully request withdrawal of the rejection.

Claims 19, 20 and 29 have only been objected to as being dependent on a rejected base claim. Such claims have been indicated as being "allowable..." and have not been rejected on the basis of any prior art. Accordingly, applicants understand that these claims are deemed by the PTO to define novel and unobvious subject matter under §§102 and 103.

Claims 19 and 29 have now been rewritten in independent form, and these claims should therefore now be in

condition for formal allowance consistent with what is stated in paragraph 9 of the Official Action.

The prior art documents made of record and not relied upon have been noted, along with the implication that such documents are deemed by the PTO to be insufficiently pertinent to warrant their application against any of applicants' claims.

Applicants respectfully await the results of a first examination on the merits.

Respectfully submitted,

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